

May 14, 2004

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via courier

RE: Interim Final Regulations Promulgated Under the Public Health
Security and Bioterrorism Preparedness and Response Act of 2002
(the "Bioterrorism Act"); Dockets 02N-0276 and 02N-0278

Dear Sir or Madam:

The American Council of Independent Laboratories (ACIL) was founded in 1937 as the national trade association representing independent scientific laboratory, testing, consulting, product certifying, and R&D firms; manufacturers' laboratories; and consultants and suppliers to the industry. ACIL defines an independent testing firm as a commercial entity engaged in analysis, testing, inspection, materials engineering, sampling, product certifying, research or development, and related consulting services for the public. An independent laboratory is not affiliated with any institution, company or trade group that might affect its ability to conduct investigations, render reports, or give professional counsel objectively and without bias. ACIL's 300 member companies operate approximately 1,500 facilities across the U.S. and abroad. They range from the one-person specialty laboratories to multi-disciplined, international corporations employing thousands of analysts, risk management specialists, consultants, and support staff. ACIL committees carry out programs of broad member interest covering issues such as laboratory accreditation, government relations, and risk management.

One of ACIL's committees is the Microbiology and Analytical Chemistry Section (MAC). MAC's mission is to promote and protect the interests of firms primarily engaged in microbiology and analytical chemistry services and to characterize composition, purity, residue, content, and contamination in the areas of food, pharmaceuticals, cosmetics, and related manufacturing industries. ACIL and the MAC Section appreciate the opportunity to comment on the FDA's interim final rules dated October 10, 2003 on *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (68 Fed. Reg. 58894) and on *Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (68 Fed. Reg. 58974) (the "Interim Final Rules").

2002N-0278

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For years, the MAC and its members have been active partners with the U.S. Food and Drug Administration (FDA), state public health agencies, and scientific organizations to protect and ensure the integrity, safety, and quality of our nation's food supply. Our members are uniquely associated with FDA's import processes. Many FDA Import Alerts require private third-party laboratory analysis of imported foods that are subject to detention without physical examination by FDA. Therefore, FDA routinely relies upon many of our members' analyses every day. This unique relationship has directly benefited the consuming public by providing further assurances that imported foods are wholesome, safe, of high quality, fresh, properly labeled, and made of appropriate ingredients. Moreover, our members' analyses and analytical reports serve FDA by reducing the government's expenditure of precious import inspection and laboratory resources while still ensuring compliance of thousands of imported shipments each year. ^{1/}

At the outset, ACIL wishes to point out that independent food laboratories are, by and large, not a part of food processing, food manufacturing, or food distribution in the United States. In fact, even those members that are affiliated with production facilities are not connected – physically or organizationally – with food production or distribution operations. Therefore, any food that may be stored, held, or imported by a food laboratory has virtually no chance of entering the U.S. food supply. Independent third party laboratories are truly set apart from food harvesting, processing, manufacturing, packing, distribution, sales, or marketing in the United States.

Independent food laboratories do, however, import samples of food into the United States and hold food prior to, during, and even after their analyses are completed. Furthermore, as discussed in more detail below, our members' analytical processes may include organoleptic examinations of domestic or imported food items by taste sensory-perception. We do not believe, however, that Congress intended to include within the definition of food consumption the process of an analyst tasting a food sample solely for conducting an organoleptic evaluation. Therefore, ACIL believes its members, and other independent third party private laboratories are exempt from the requirement to register their facilities.

Moreover, ACIL believes that extending FDA's prior notice requirements to food samples imported solely for scientific analysis, even if it may be subjected to taste testing, creates a substantial burden upon our members and other similarly situated independent private laboratories. Further, requiring prior notice of imported analytical food samples will not result in any reduction of risk to the public or the nation's food

^{1/} FDA recently noted these benefits in its proposed rule affecting private laboratories and sampling services used in connection with imported foods. See *Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food*, 69 FR 23460, 23461 (Apr. 29, 2004).

supply. We note that in FDA's recent Federal Register notices and guidance, the agency has adopted particular language for determining when prior notice is required for "multiple use" articles that accommodates ACIL's proposal to expressly exempt imported analytical food samples from the prior notice requirement.

Applicability of FDA's Registration Regulations to the Private Laboratory Industry

As we mentioned briefly above, one aspect of a traditional analytical food laboratory's operations may include "taste testing." Even though FDA has largely abandoned taste testing, ^{2/} sensory perception by taste and the other senses remains one of the most sensitive analytical techniques available for detecting certain chemicals that form during the degradation of many food products. As food degrades chemicals are formed that produce higher flavor notes than would be expected in a fresh product. This is true, for instance, when fat breaks down over time. In fact, some chemicals can be detected by an expert tasting the food at the "part per trillion" (ppt) concentration level – well below the detection level of any modern analytical equipment.

By way of example, nonadienal and decadienal are both natural products of fat oxidation. Organoleptic analysis for these compounds can detect their presence at 100 ppt whereas gas chromatography and mass spectrum analyses are able to detect them only at 1 part-per-million (ppm) and higher. ^{3/} Additionally, an organoleptic expert can detect trichloroanisol, a breakdown product of pentachlorophenol, at 1 ppt. ^{4/} Pentachlorophenol is a wood preservative that may taint wine. Analytical equipment can only reliably detect trichloroanisol at levels at or above 100 ppt. Furthermore, blue-green algae and actinomycete bacteria produce geosmin in water that may become

^{2/} We note, however, that several documents available on FDA's internet site refer to taste testing as a current means for detecting decomposed and diseased nuts and nut products, the presence of various herbs, and even contamination of seafood caused by oil spills. See e.g., MACROANALYTICAL PROCEDURES MANUAL, NUTS AND NUT PRODUCTS, FDA Technical Bulletin No. 5, at <http://www.cfsan.fda.gov/~dms/mpm-8.html> (1998) ("[Brazil nut] kernels suspected of being rancid or otherwise decomposed should be tasted as necessary.") See *Draft Report of the Food Advisory Committee Dietary Supplement Working Group On Ingredient Identity, Testing Records and Retention*, at <http://www.cfsan.fda.gov/~dms/facgmp.html> (June 25, 1999) ("Testing techniques include . . . [c]haracteristic color, smell, and taste.") See also Cohn, Jeffrey P., *On the Trail of the Alaskan Oil Spill*, at <http://www.fda.gov/bbs/topics/CONSUMER/CON00067.html> (FDA CONSUMER, April 1990) ("spotting signs of oil contamination . . . requires using one's senses of sight, smell, touch, and sometimes taste") (citing an interview with FDA lead organoleptic analyst Richard Throm).

^{3/} See e.g., *Compilation of Odor and Taste Threshold Values Data*, American Society for Testing and Materials, ASTM Data Series DS48A, 1978.

^{4/} See *id.*

incorporated into foods. Although humans can detect an earthy taste in foods at 20 ppt geosmin, analytical instruments can only detect it in foods at or above 10 ppm. ^{5/}

As the above clearly demonstrates the human body's sensory organs, including the tongue, remain the most efficient and sensitive scientific instruments available for many types of analyses.

Taste testing is not limited, however, to detecting degradation of food over time. It is also used in product development. Trained and experienced organoleptic scientists may be presented with an array of samples, each with slightly different formulations, and asked to compare the presence of certain desirable flavor notes that are distinctive to a brand. Conversely, a food client may wish to avoid certain flavor notes and organoleptic analyses can detect and assist in developing proper formulations.

None of these processes, however, are "consumption", as that term is ordinarily conceived. The organoleptic scientist is not consuming the article for enjoying its "taste, aroma, or nutritive value." See *Nutrilab, Inc., v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983). See also 68 FR 58894, 58909 (Oct. 10, 2003). Therefore, even if a scientific organoleptic analysis of a food item requires a scientist to test a food sample by tasting it, FDA should agree that this process is not "consum[ption] in the United States" for applying FDA's registration rule. *Id.* at 58912. Food samples are not "food for consumption" – a distinction that FDA has already relied upon to exempt food-contact materials from the registration requirement. *Id.* at 58909 (emphasis added).

ACIL believes this conclusion is supported by the fact that our members routinely destroy food sample remainders after conducting their analyses, except for a small portion that may be kept in a sample library as a retention sample. Therefore, there is virtually no risk that the food analyzed by private, independent laboratories will be directed into the U.S. food supply.

The primary question, then, is whether an organoleptic analysis involving food tasting for scientific purposes constitutes consumption. We urge FDA to expressly agree that it does not.

FDA stated in the preamble to the interim final registration rule that:

^{5/} See e.g., Birch, G. G., & Lindley, M. G., (Eds.):. *Developments in Food Flavours*. Elsevier, New York. pp. 249-273 (1986). See also, *Compilation of Odor and Taste Threshold Values Data*, American Society for Testing and Materials, ASTM Data Series DS48A, 1978 (Environmental Protection Agency odor threshold in air is 180 ppt).

R&D facilities and sample facilities that manufacture/process, pack, or hold food that is consumed in the United States, either by the facility's employees or others are required to register. However, if R&D facilities and sample facilities manufacture/process, pack or hold food and this food is not for consumption or actually consumed in the United States, the facilities are not subject to registration.

68 FR 58912.

Based upon this language, the MAC is discussing development of a code of conduct that would prohibit member employees by company policy from consuming the remainder of any food sample received at the laboratory for analysis. We believe this addresses FDA's primary concern regarding food consumption that may be associated with "R&D facilities or sample facilities." *Id.* Consequently, if food sample remainders are properly destroyed after they are analyzed in accordance with the laboratory's policies and procedures for handling such remainders, the laboratory's facilities are not subject to FDA's registration rule. ^{6/} But for the organoleptic analysis of food samples by food laboratory scientists, the laboratory facilities are not subject to the registration regulation.

Therefore, we request that FDA agree and clarify through agency guidance that "taste-testing", as part of a scientifically based organoleptic analysis by an analyzing laboratory, is not "consumption" for the purposes of FDA's bioterrorism regulations.

We believe that this result is consistent with the purposes behind the new Bioterrorism Act. The new registration authority was not constructed to necessarily prevent the use of a food article as a vector for a biological or chemical agent. Rather it was designed primarily to aid the FDA and other public health agencies and services in mitigating the potential harm such an event might cause and to trace the affected article back to its source. In the case of food samples being analyzed organoleptically, the risk that a contaminated food sample could be spread throughout the food chain is barely cognizable. The analyst would be the only affected party and the sample remainder would already have been destroyed or would be securely locked in a sample closet or in a retention inventory. As for the source of the affected food, our members only perform laboratory services at the request of their clients. Consequently, there would be no

^{6/} ACIL believes that FDA could clarify that this proposed exemption for independent private laboratories applies only to laboratory facilities that destroy all food sample remainders except for small retention samples. This would ensure that laboratories that do not follow this procedure or adopt the MAC's code of conduct would remain subject to FDA's requirements under the registration rule.

difficulty in tracing the food sample to the immediate previous supplier. The protections promoted by the registration (and record keeping) rule are unnecessary in the independent food laboratory industry.

Applicability of FDA's Prior Notice Regulations to the Private Laboratory Industry's Import Activities

Our members are particularly concerned about the applicability of FDA's interim final prior notice regulation. 68 FR 58974 (Oct. 10, 2003). Under the prior notice rule, an electronic prior notice must precede virtually all food imports before any food actually arrives in the United States. *Id.* at 58977. Our members have many foreign and multi-national clients who seek various scientific analyses on food from other countries. FDA has stated that even imported food samples, whether for analysis, marketing, or research and development, are subject to the prior notice requirements. This is particularly onerous for our members.

As discussed above, food samples imported by private independent laboratories are legally distinguishable from food articles imported for human or animal consumption. In addition, there is great variety in the ways and conditions under which such samples arrive in the United States. The samples may be in retail packaging or in collection containers. They may be labeled in compliance with federal law or may lack required or English labeling. The samples may arrive in multiple packaging varieties and sample container sizes and these many variations may be found in the same imported shipment to a food laboratory. Therefore, each food sample shipment could result in dozens of separate prior notice submissions due to FDA's mandatory prior notice data requirement to provide the estimated quantity of imported food, including the packaging description for each separate "article" of food. See 68 FR at 58978. See *also* 21 C.F.R. § 1.281(a)(5)(iii).

As a result every food sample in each shipment often requires a separate prior notice, producing dozens of prior notices for such shipments – for thousands of shipments each year. In each instance, however, the sample is imported by and delivered to an independent laboratory that is unconnected with food processing, manufacturing, or distribution for US consumption. Therefore, applying the prior notice authorities to imported food samples for laboratory analyses creates substantial burdens on the private laboratory industry and the FDA's Prior Notice and electronic screening systems, and mitigates no identifiable security or safety risks.

Imported Food Samples for Laboratory Analyses are "Multiple Use" Articles

ACIL believes that under FDA's prior notice rule, imported food samples intended for scientific analysis are articles with "multiple uses". See 68 FR 58986-87. As demonstrated above, such samples:

- are intended solely for scientific analyses;
- are not consumed for flavor, aroma, or nutritional value;
- have virtually no chance of being diverted into the U.S. food supply;
- are destroyed after completion of the analysis, but for very small retention portions; and
- are maintained at all times in secure sample closets or retention inventories.

FDA has created a standard for determining whether prior notice is required for an imported item with multiple uses, saying:

FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use. *Id.*

In the case of analytical samples imported solely for scientific analyses, no person associated with the importation has any expectation that the item will be directed to food use. Discarding sample remainders and maintaining a small portion of retention samples in locked inventories further removes any risk that the food samples could be converted or diverted to a food use.

We further emphasize a lack of any real bioterrorism threat associated with these samples. They are often shipped by way of express courier, which renders them capable of being tracked throughout the shipping process to the destination. This mode of shipment also enables our members to maintain a proper chain of custody for each sample. These efforts have not only proven effective for avoiding shipping losses but also enhance sample traceability, should it become necessary to identify where any given sample has been.

Therefore, ACIL and the MAC argue that imported samples for scientific analyses are multiple use items and are not subject to the prior notice rule unless the persons associated with their importation reasonably believe the samples are reasonably expected to be directed to a food use.

* * *

In summary ACIL asks FDA to agree and expressly state in FDA guidance that:

- Organoleptic analysis of analytical samples, even if such analysis may include "taste-testing" of small quantities of a food sample, does not constitute "consumption" of food for purposes of FDA's Bioterrorism regulations.

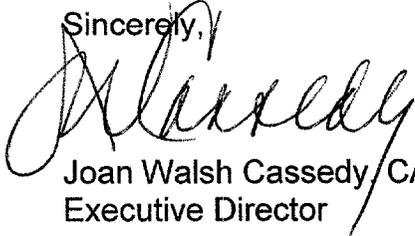
Therefore,

- Independent private laboratories are exempt from FDA's registration rule even if they store food samples that may be subject to such organoleptic analyses; and
- FDA's prior notice rule does not apply to an imported analytical sample unless the persons associated with importing the sample reasonably believes the sample is reasonably expected to be directed to a food use.

ACIL recognizes its proposed exemptions would not apply to a laboratory facility that directs its samples, sample remainders, or retention samples for consumption other than organoleptic analyses.

ACIL and MAC again wish to convey our appreciation for the opportunity to provide comment on FDA's interim final Bioterrorism rules. We remain at your disposal for any information and assistance that will facilitate the smooth implementation of FDA's regulatory oversight under the Bioterrorism Act.

Sincerely,



Joan Walsh Cassedy, CAE
Executive Director